PHYSICIAN LABELING
Alcon Laboratories, Inc.

ACRY
ReSTOR
apodized diffractive IOL

STERILE UV-Absorbing Acrylic Foldable
Apodized Diffractive Optic Posterior Chamber Intraocular Lenses

CAUTION: Federal (U.S.) law restricts this device to the sale by or order on the order of a physician.

DESCRIPTION

The ACRYSOF® ReSTOR® Apodized Diffractive Optic Posterior Chamber Intraocular Lens (IOL) is a UV-absorbing foldable multifocal intraocular lens (IOL). The optical portion is biconvex and consists of a high refractive index soft acrylic material capable of being folded prior to insertion, allowing placement through an incision smaller than the optic diameter of the lens. After surgical insertion into the eye, the lens gently unfolds to restore the optical performance. The supporting haptics provide for proper positioning of the IOL optic within the eye.

Figure 1: Physical Characteristics, ACRYSOF® ReSTOR® Models SA60D3 and MA60D3 (all dimensions in millimeters)

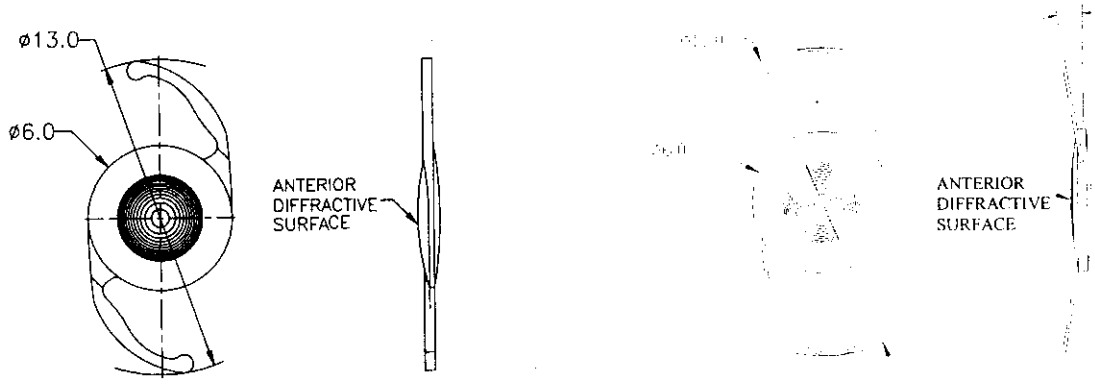
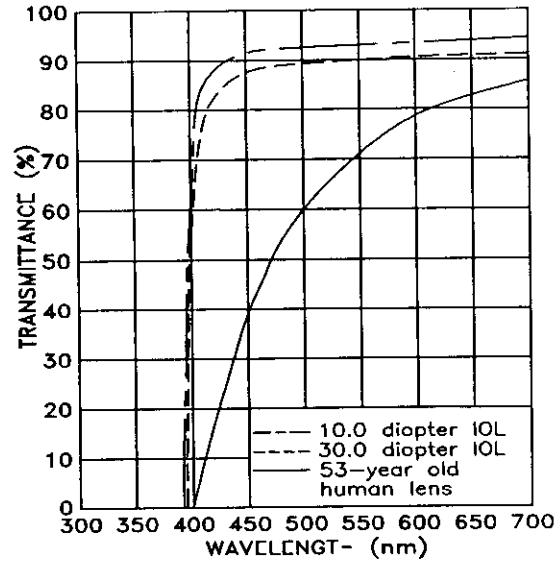


Table 1: Physical Characteristics of ACRYSOF® ReSTOR® Apodized Diffractive Optic IOLs

Characteristics	Model	
	SA60D3 Single-piece	**MA60D3** Multi-piece
Optic Type	Apodized Diffractive Optic	
Optics Material	Ultraviolet-absorbing Acrylate/Methacrylate Copolymer UV cutoff at 10% T: 398 nm (+10.0 diopter lens) 400 nm (+30.0 diopter lens)	
Optic Powers	For available base power range see Alcon Product Guide (+ 4.0 diopters of add power for near vision)	
Index Of Refraction	1.55	
Haptic Configuration	STABLEFORCE®	Modified-C
Haptic Material	See optic material	PMMA (MONOFLEX™1)
Haptic Color	Clear	Blue
Optic Diameter (mm)	6.0	
Overall Length (mm)	13.0	
Haptic Angle	0°	10°

Figure 2: Spectral Transmittance Curves
(percentage transmittance)

NOTES:
- The cutoff wavelength and the spectral transmittance curves presented here represent the range of transmittance values of IOL's made from Acrylate/methacrylate Copolymer with bonded UV-absorber.
- Measurements were direct transmittance using a 6 mm aperture and a disc of thickness equivalent to the optic center.
- UV cutoff at 10% T is 398 nm (+10 diopter lens). UV cutoff at 10% T is 400 nm (+30 diopter lens).
- Human lens data from Boettner and Wolter (1962).



MODE OF ACTION

ACRYSOF® ReSTOR® Apodized Diffractive Optic IOLs are intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. These IOLs have a biconvex optic containing an apodized diffractive structure that provides increased depth of focus.

INDICATIONS

The ACRYSOF® ReSTOR® Apodized Diffractive Optic Posterior Chamber Intraocular Lens (IOL) is intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. The lens is intended to be placed in the capsular bag.

WARNINGS

1. Some visual effects may be expected due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or radial lines around point sources of light under nighttime conditions.
2. A reduction in contrast sensitivity as compared to a monofocal IOL may be experienced by some patients and may be more prevalent in low lighting conditions. Therefore, multifocal patients should exercise caution when driving at night or in poor visibility conditions.
3. The physician should consider the following points that are unique to the use of the ReSTOR® IOL:
   - The surgeon must target emmetropia to achieve optimal visual performance.
   - Patients with significant preoperative (determined by keratometry) or expected postoperative astigmatism >1.0D may not achieve optimal visual outcomes.
   - Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions.

PRECAUTIONS

1. Prior to surgery, prospective patients must be provided with a copy of the Patient Information Brochure for this product and informed of the possible risks and benefits associated with the ACRYSOF® ReSTOR®.
2. Posterior capsule opacification (PCO), when present, developed earlier into clinically significant PCO with the ReSTOR lenses as compared to the monofocal control.

3. The safety and effectiveness of the ReSTOR IOL have not been substantiated in patients with preexisting ocular conditions and intraoperative complications (see below). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions.

   Before Surgery
   - Significant irregular corneal aberration
   - Retinal conditions or predisposition to retinal conditions, previous history of, or a predisposition to, retinal detachment or proliferative diabetic retinopathy, in which future treatment may be compromised by implanting this lens.
   - Amblyopia
   - Clinically severe corneal dystrophy (e.g., Fuchs')
   - Rubella, congenital, traumatic or complicated cataracts
   - Extremely shallow anterior chamber, not due to swollen cataract
   - Recurrent anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye (e.g. iritis or uveitis).
   - Aniridia
   - Iris neovascularization
   - Glaucoma (uncontrolled or controlled with medication)
   - Microphthalmos or macrophthalmos
   - Optic nerve atrophy
   - Previous corneal transplant
   - Pre-existing ocular conditions which may negatively impact stability of the implant.

   During Surgery
   - Mechanical or surgical manipulation required to enlarge the pupil
   - Vitreous loss (significant)
   - Anterior chamber bleeding (significant)
   - Uncontrollable positive intraocular pressure
   - Complications in which the IOL stability could be compromised

   Physicians considering lens implantation in such patients should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternatives are deemed unsatisfactory in meeting the needs of the patient.
4. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
5. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
6. As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma, and secondary surgical intervention. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.
7. Care should be taken to remove viscoelastic from the eye at the close of surgery.
8. Do not resterilize these intraocular lenses by any method.
9. Do not store intraocular lenses at temperatures over 45°C (113°F)
10. Use only sterile intraocular irrigating solutions (such as BSS or BSS Plus) to rinse and/or soak lenses.

CALCULATION OF LENS POWER

Good biometry is essential to successful visual outcomes. Preoperative calculation of required lens power for the ACRYSOF® ReSTOR® should be determined by the surgeon's experience, preference, and intended lens placement. The A-constant listed below is presented as a starting point for implant power calculations. Lens constants must be "personalized" to compensate for the differences in instrumentation, measurement technique, and IOL power calculation methods that exist between different clinical sites. To achieve optimal results with the apodized diffractive optic IOL, it is important to use a personalized lens constant, and a convenient initial estimate can be obtained by referencing to the personalized lens constant for a similar lens model. As an example, using the SA60AT or MA60BM lens models for comparison, the A-constant for the SA60D3 and MA60D3 can be predicted. These provisional A-constants have been estimated from lens design data and confirmed by clinical results.

Table 2: Calculations of ACRYSOF® ReSTOR® Lens Power

Model	A-constant
SA60D3	118.1 D
MA60D3	118.3 D

Hoffer, K.J., The Hoffer Q formula: A comparison of theoretic and regression formulas. J. Cataract Refract. Surg. 19:700-712, 1993.

Holladay, J.T., et al., A three part system for refining intraocular lens power calculations. J. Cataract Refract. Surg, 14:17-24, 1988.

Holladay, J.T., et al., Standardizing constants for ultrasonic biometry, keratometry, and IOL power calculations, J. Cataract Refract. Surg. 23:1356-1370, 1997.

Retzlaff, J.A., Sanders, D.R., and Kraff, M. Lens Implant Power Calculation, 3rd ed., Slack, Inc., Thorofare, N.J., 1990.

DIRECTIONS FOR USE

1. Examine the label on the unopened package for model, powers (base and add), proper configuration, and expiration date.
2. After opening the cardboard storage container, verify lens case information (e.g., model, power, and serial number) is consistent with information on outer package labeling.
3. This device is sterile until the inner pouch is opened. Inspect the pouch carefully for tears, cuts, punctures or other signs that the pouch has been opened or damaged. DO NOT implant the IOL if the sterility has been compromised. (See RETURNED GOODS POLICY).
4. To remove the lens, open the undamaged pouch and transfer the case to a sterile environment. Carefully open the case to expose the lens.
5. To minimize the occurrence of marks on the lens due to handling, all instrumentation should be scrupulously clean. Any forceps used for lens handling must have round edges and smooth surfaces.
6. When removing the lens from the case, DO NOT grasp the optical area with forceps. The IOL should only be handled by the haptics. Handle lenses carefully to avoid damage to lens surfaces or haptics. DO NOT attempt to reshape haptics in any way.
7. Rinse the lens thoroughly using sterile intraocular irrigating solution such as BSS® or BSS PLUS®. Prior to insertion the lens should be carefully examined to ensure that particles have not adhered during handling.
8. Alcon recommends using the MONARCH® B cartridge with the MONARCH® II delivery system, or equivalent Alcon approved delivery system.
9. There are various surgical procedures that can be utilized, and the surgeon should select a procedure that is appropriate for the patient. Current techniques, appropriate instrumentation, and a list of their equivalents for delivery and implantation are available from Alcon. Surgeons should verify that appropriate instrumentation is available prior to surgery.
10. DO NOT reuse this IOL. This device is for single use only.

PATIENT REGISTRATION AND REPORTING

Each patient must be registered with Alcon Laboratories, Inc. immediately following implantation of one of these lenses. Registration is accomplished by completing the prepaid Implant Registration Card that is enclosed in the lens box and mailing it to Alcon Laboratories, Inc. Patient registration is essential for Alcon

Laboratories, Inc. long-term patient follow-up program and will assist us in responding to adverse event reports. The Patient Identification Card included in the package is to be completed and given to the patient, together with instructions to keep the card as a permanent record to be shown to any eye care practitioner the patient consults in the future.

Adverse events that may reasonably be regarded as lens-related and that were not previously expected in nature, severity, or degree of incidence should be reported to Alcon Laboratories, Inc. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation. Surgeons should use the following address and telephone number for reporting adverse events involving these intraocular lenses:

Alcon Laboratories, Inc., Technical Consumer Affairs (S3-14)
6201 South Freeway, Fort Worth, Texas 76134.
Call Collect: (817) 551-4445.

Outside the United States, contact local Alcon offices or distributors regarding reports of adverse events.

ACRYSOF® RESTOR® APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL CLINICAL STUDIES

Overview of Clinical Studies

Multicenter clinical studies were conducted in the United States and Europe to establish the safety and effectiveness of the AcrySof® ReSTOR® Apodized Diffractive Optic IOL (Models MA60D3 and SA60D3). A total of 566 first-eye implanted ReSTOR® IOL (440 MA60D3 and 126 SA60D3) and 194 AcrySof® MA60BM Monofocal Control patients comprise the All Implanted cohort. A Best Case cohort (no clinically significant preoperative ocular pathology or postoperative macular degeneration) consists of 391 MA60D3 and 109 SA60D3 ReSTOR® IOL patients and 172 Monofocal Control patients. Demographically, these studies consisted of 65.3% female and 34.7% male patients. Stratifying by race, there are 93.9% Caucasian, 2.6% Black, 0.9% Asian and 2.5% designated "Other" race. The mean age for the total population is 68.8 years.

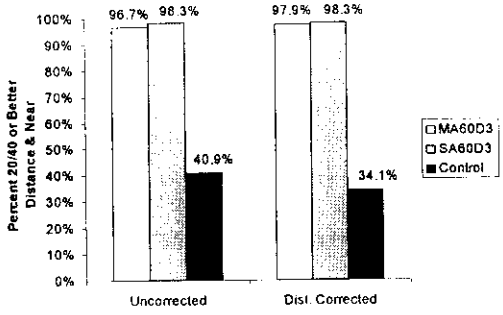
Visual Acuity
ReSTOR subjects experienced a significant increase (≥2 lines) in uncorrected photopic and distance corrected photopic near vision as compared to monofocal control patients. The improvement in distance corrected near vision was greater under photopic than mesopic conditions. Mean spherical add power needed to achieve best corrected near visual acuity was higher under mesopic conditions (mean value of 2.5 D) than photopic conditions (range of mean values: 0.09 to 0.16 D). The average distance of best focus for near vision was approximately 2 cm closer than the predicted distance of 33 cm.

Results from a controlled clinical study revealed that maximum visual performance is achieved when implanted bilaterally. Binocularly implanted ReSTOR subjects achieved uncorrected and best corrected distance visual acuities similar to monofocal control subjects. When implanted monocularly, a statistically significant decrease (≤2 letters) in mean uncorrected and best corrected distance visual acuity was observed in subjects with ReSTOR as compared to the monofocal controls. Older subjects implanted with the ReSTOR lens (e.g. ≥ 80 years old), demonstrated a trend for poorer uncorrected distance visual acuity than the monofocal control patients.

Binocular Visual Acuity

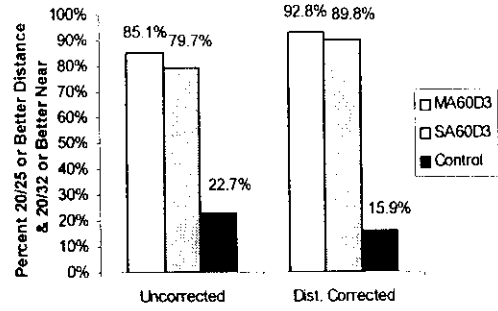
The following is a summary of binocular visual acuity (VA) results for patients who completed the Form 4A (120-180 days after second eye implantation).

Figure 3-A:
Combined 20/40 or Better Distance & Near Photopic Visual Acuity



Binocular, Best Case
6 Months Postoperative

Figure 3-B:
Combined 20/25 or Better Distance & 20/32 or Better Near Photopic Visual Acuity



Binocular, Best Case
6 Months Postoperative

Table 3:
Cumulative Binocular Photopic Near Visual Acuity by Lens Model, All Implanted, 6 Months Postoperative

		Sample size	20/20 (J0) or better	20/25 (J1) or better	20/32 (J2) or better	20/40 (J3) or better	Worse than 20/40 (J3)
		N	%	%	%	%	%
Uncorrected (Best Distance)	MA60D3	388	38.9	74.5	90.5	96.4	3.6
	SA60D3	69	46.4	69.6	87.0	98.6	1.4
	Monofocal	157	3.2	14.0	23.6	40.8	59.2
Uncorrected (Standard Distance)	MA60D3	388	36.9	69.1	87.9	95.9	4.1
	SA60D3	69	42.0	69.6	87.0	98.6	1.4
	Monofocal	157	0.6	2.5	8.9	26.1	73.9
Distance Corrected (Best Distance)	MA60D3	387	45.5	76.2	92.5	97.9	2.1
	SA60D3	69	43.5	76.8	88.4	97.1	2.9
	Monofocal	157	1.9	5.7	15.9	33.8	66.2
Distance Corrected (Standard Distance)	MA60D3	387	47.5	77.5	93.8	97.9	2.1
	SA60D3	69	44.9	76.8	89.9	98.6	1.4
	Monofocal	157	0.6	3.8	8.3	21.0	79.0
Best Corrected (Standard Distance)	MA60D3	387	54.3	85.0	96.4	98.4	1.6
	SA60D3	68	58.8	85.3	95.6	98.5	1.5
	Monofocal	157	52.9	79.6	94.3	96.8	3.2

Table 4:
Cumulative Binocular Photopic Distance Visual Acuity by Lens Model, All Implanted, 6 Months Postoperative

		Sample size	20/20 or better	20/25 or better	20/32 or better	20/40 or better	Worse than 20/40
		N	%	%	%	%	%
Uncorrected	MA60D3	388	64.2	88.1	95.1	99.2	0.8
	SA60D3	69	58.0	88.4	95.7	100.0	0.0
	Monofocal	157	70.7	91.7	94.9	97.5	2.5
Best Corrected	MA60D3	387	89.4	97.9	100.0	100.0	0.0
	SA60D3	69	88.4	100.0	100.0	100.0	0.0
	Monofocal	157	93.0	97.5	98.7	100.0	0.0

Monocular Visual Acuity

The following is a summary of monocular visual acuity (VA) results for patients who completed the Form 4 (120-180 days after first eye implantation), and Form 5 (330-420 days after first eye implantation) exams.

Table 5:
Cumulative Monocular Photopic Near Vision by Lens Model, All Implanted, 6 Months Postoperative

		Sample size	20/20 (J0) or better	20/25 (J1) or better	20/32 (J2) or better	20/40 (J3) or better	Worse than 20/40 (J3)
		N	%	%	%	%	%
Uncorrected (Best Distance)	MA60D3	407	27.3	51.8	74.9	86.2	13.8
	SA60D3	110	28.2	53.6	79.1	90.0	10.0
	Monofocal	176	1.1	5.7	12.5	26.1	73.9
Uncorrected (Standard Distance)	MA60D3	407	19.2	42.5	67.6	84.5	15.5
	SA60D3	110	19.1	41.8	67.3	85.5	14.5
	Monofocal	176	0.0	0.6	6.8	11.9	88.1
Distance Corrected (Best Distance)	MA60D3	407	30.2	58.2	83.0	92.1	7.9
	SA60D3	110	30.9	63.6	86.4	94.5	5.5
	Monofocal	176	0.6	2.3	9.1	21.6	78.4
Distance Corrected (Standard Distance)	MA60D3	407	26.8	59.0	81.1	92.9	7.1
	SA60D3	110	30.0	64.5	80.9	96.4	3.6
	Monofocal	176	0.6	1.1	3.4	11.4	88.6
Best Corrected (Standard Distance)	MA60D3	406	35.5	70.7	88.4	95.6	4.4
	SA60D3	110	36.4	77.3	90.0	97.3	2.7
	Monofocal	176	34.7	67.0	85.2	94.9	5.1

Table 6:
Cumulative Monocular Photopic Distance Vision by Lens Model, All Implanted, 6 Months Postoperative

		Sample size	20/20 or better	20/25 or better	20/32 or better	20/40 or better	Worse than 20/40
		N	%	%	%	%	%
Uncorrected	MA60D3	407	33.2	59.2*	77.1*	90.2	9.8
	SA60D3	110	29.1	53.6*	80.0*	92.7	7.3
	Monofocal	176	42.0	71.6	85.8	94.9	5.1
Best Corrected	MA60D3	407	73.5*	92.6	97.1	99.3	0.7
	SA60D3	110	77.3*	92.7	98.2	100.0	0.0
	Monofocal	176	84.7	96.0	98.3	99.4	0.6

*Statistically significant difference versus monofocal control

Table 7:
Cumulative Monocular Photopic Near Vision by Lens Model, All Implanted, 1 Year Postoperative

		Sample size	20/20 (J0) or better	20/25 (J1) or better	20/32 (J2) or better	20/40 (J3) or better	Worse than 20/40 (J3)
		N	%	%	%	%	%
Uncorrected (Best Distance)	MA60D3	319	21.0	53.6	74.9	85.6	14.4
	Monofocal	89	3.4	4.5	11.2	19.1	80.9
Uncorrected (Standard Distance)	MA60D3	319	17.9	43.6	69.6	79.6	20.4
	Monofocal	89	0.0	0.0	2.2	12.4	87.6
Distance Corrected (Best Distance)	MA60D3	318	30.5	62.9	82.1	90.9	9.1
	Monofocal	89	0.0	1.1	3.4	14.6	85.4
Distance Corrected (Standard Distance)	MA60D3	319	29.5	60.5	80.6	90.3	9.7
	Monofocal	89	0.0	1.1	2.2	9.0	91.0
Best Corrected (Standard Distance)	MA60D3	319	36.4	70.2	89.3	94.7	5.3
	Monofocal	89	50.6	79.8	94.4	95.5	4.5

Table 8:
Cumulative Monocular Photopic Distance Vision by Lens Model, All Implanted, 1 Year Postoperative

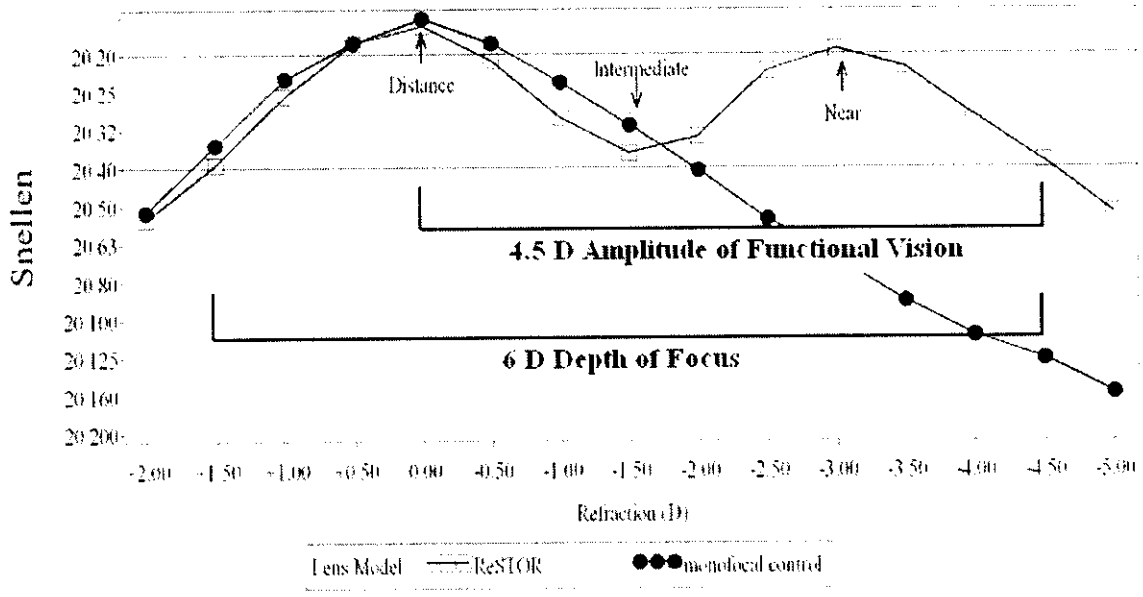
		Sample size	20/20 or better	20/25 or better	20/32 or better	20/40 or better	Worse than 20/40
		N	%	%	%	%	%
Uncorrected	MA60D3	319	30.1	58.9*	76.8*	90.0	10.0
	Monofocal	89	42.7	78.7	89.9	95.5	4.5
Best corrected	MA60D3	319	74.6*	93.4	97.8	99.1	0.9
	Monofocal	89	87.6	94.4	98.9	100.0	0.0

*Statistically significant difference versus monofocal control

Clinical Sub-studies

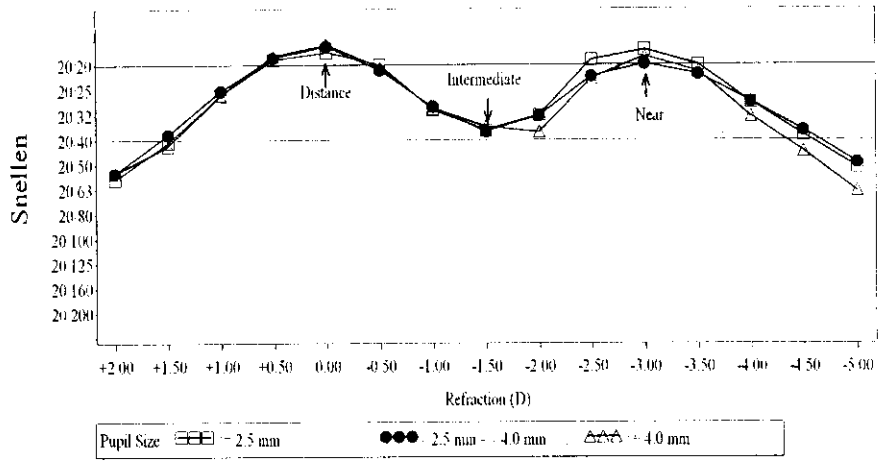
Defocus
A binocular refraction defocus curve from the United States Intermediate Vision Study (34 ACRYSOF® ReSTOR® MA60D3 All Implanted patients) displays two peaks, with one at the zero baseline corresponding to the distance focal point of the lens and one near the –3.0 D of correction, which corresponds to the near focal point of the lens. The distance peak of this curve demonstrates that ReSTOR® IOL patients achieved a mean distance visual acuity of 20/20 or better, with an additional increased depth of focus from -2.0 D to -4.5 D as compared to monofocal control patients (N = 27). This additional increased depth of focus translates to a mean intermediate visual acuity of 20/40 or better and is most pronounced at near, with up to a five-line visual acuity improvement for patients implanted with a ReSTOR® IOL versus the Monofocal Control (Figure 4).

Figure 4:
Mean Defocus Curves by Lens Model, Binocular, All Implanted



These data demonstrate that the ReSTOR® IOL provides a 4.5 diopter amplitude of functional (20/40 or better) vision (from optical infinity to approximately 22 cm). Binocular performance of the ReSTOR IOL was approximately 0.5 lines better for near vision and 1.5 lines better for intermediate vision than the monocular performance of the ReSTOR IOL. Additionally, the defocus curves were within 1 line among groups when stratified by pupil size (Figure 5).

Figure 5:
Mean Defocus Curves by Pupil Size
Binocular, All Implanted (N=34)



Intermediate Vision

In addition to the clinical studies supporting the safety and effectiveness of ACRYSOF® ReSTOR® IOL Models MA60D3 and SA60D3, a parallel group (N=34), non-randomized, multi-center supplemental study was conducted in the U.S. to evaluate the performance of the ACRYSOF® ReSTOR® IOL Model MA60D3 for intermediate vision compared to the monofocal control, ACRYSOF IOL Model MA60BM. At a distance of 70 cm, the percentage of eyes achieving 20/20 or better uncorrected vision and 20/25 or better distance corrected vision was significantly worse for the ReSTOR IOL as compared to the monofocal control. No statistical differences were observed between the ReSTOR IOL and the monofocal control lens for uncorrected and distance corrected vision 20/32 or better when tested at 50, 60 or 70 cm.

Table 9:
Intermediate Photopic Visual Acuity,
Binocular, All Implanted

			Percent 20/40 or better		
		Total Sample Size	50 cm	60 cm	70 cm
Uncorrected	ReSTOR	34	82.4*	85.3	67.6
	Control	27	59.3	66.7	63.0
Distance Corrected	ReSTOR	34	64.7	70.6	52.9
	Control	27	59.3	66.7	77.8

*=Statistically different from control at 0.05 level

Low Contrast Visual Acuity and Contrast Sensitivity
Contrast sensitivity and low contrast acuity under various lighting conditions was clinically equivalent between ReSTOR® IOL and Monofocal Control patients. While there was a tendency for reduced contrast sensitivity and low contrast acuity in ReSTOR® IOL patients in low lighting (mesopic) conditions when exposed to a glare source, no differences in contrast sensitivity from the monofocal control exceeded more than 0.3 log units, and no difference in low contrast acuity exceeded more than 2 Snellen lines.

Low contrast acuity results were comparable between ReSTOR® IOL and Monofocal Control groups measured with Regan contrast charts at all light sources and gray scales (100%, 25% and 9%). Functional vision (20/40 or better) was maintained under photopic conditions at all gray scales with and without glare and under mesopic conditions at 100% and 25% with and without glare.

A Vector Vision (CSV1000) contrast sensitivity chart that employs a full range of sine wave gratings at 9 contrast levels and 4 spatial frequencies (3, 6, 12, and 18 cpd) was used to assess contrast sensitivity under photopic (85 cd/m^2) and mesopic (2-5 cd/m^2) conditions, with and without a glare source. Statistical and descriptive comparisons of contrast sensitivity of the ACRYSOF® ReSTOR® versus the Monofocal Control indicate that, while there are measurable differences between the two groups at higher spatial frequencies when tested under the same photopic and mesopic conditions with and without glare, none of these differences exceeded 0.3 log units. At certain spatial frequencies, the ACRYSOF® ReSTOR® IOL Model SA60D3 performed statistically significantly better than the ACRYSOF® ReSTOR® IOL Model MA60D3 by at least 0.128 log units under monocular mesopic with and without glare conditions and by 0.143 log units under binocular mesopic with glare conditions. Additionally, for monocular contrast sensitivity testing, there was no difference in the percentage of ReSTOR and monofocal control patients who were not able to see any of the gratings. For binocular contrast sensitivity testing at least 85% of patients in both the ReSTOR and monofocal control groups were able to see at least one grating, with the exception of mesopic with glare testing at 12 and 18 cycles per degree. At these spatial frequencies, the percentage of ReSTOR patients able to see at least one grating ranged from 85.9% - 75.0% as compared to 95.8% - 90.6% of Monofocal Control patients.

Table 10:
Mean Log Decrease in Contrast Sensitivity
ReSTOR Compared to Monofocal Control Under Photopic, Mesopic and Glare Conditions, Monocular, All Implanted, 6 Months Postoperative

		Spatial Frequency (c/d)			
Light Source	Model	A(3)	B(6)	C(12)	D(18)
Photopic w/o Glare	MA60D3	-0.02	-0.04	-0.09	-0.05
	SA60D3	0.01	-0.03	-0.12	-0.09
Photopic w/ Glare	MA60D3	-0.06	-0.15	-0.15	-0.15
	SA60D3	-0.05	-0.14	-0.18	-0.16
Mesopic w/o Glare	MA60D3	0.00	-0.12	-0.13	-0.09
	SA60D3	0.00	-0.02	0.00	-0.04
Mesopic w/ Glare	MA60D3	-0.08	-0.11	-0.12	-0.12
	SA60D3	-0.01	-0.04	-0.02	-0.06

Table 11:
Mean Log Decrease in Contrast Sensitivity
ReSTOR Compared to Monofocal Control Under Photopic, Mesopic and Glare Conditions, Binocular, All Implanted, 6 Months Postoperative

		Spatial Frequency (c/d)			
Light Source	Model	A(3)	B(6)	C(12)	D(18)
Photopic w/o Glare	MA60D3	-0.03	-0.11	-0.17	-0.12
	SA60D3	-0.06	-0.15	-0.21	-0.16
Photopic w/ Glare	MA60D3	-0.07	-0.23	-0.22	-0.17
	SA60D3	-0.10	-0.24	-0.23	-0.24
Mesopic w/o Glare	MA60D3	-0.06	-0.12	-0.26	-0.18
	SA60D3	-0.07	-0.17	-0.23	-0.19
Mesopic w/ Glare	MA60D3	-0.15	-0.24	-0.25	-0.19
	SA60D3	-0.07	-0.24	-0.23	-0.21

Driving Sub-study
Night driving performance was tested using the NDS (Night Driving Simulator) developed and validated by Vision Sciences Research, Corp. Bilaterally implanted patients (23 ReSTOR® IOL Model MA60D3 Patients and 25 monofocal controls) were tested to determine visibility distances for the detection and identification of road warning signs, message signs and road hazards under various conditions. The

simulated driving scenes were a city street at night with streetlights and a rural highway with low beam headlights. Testing in both driving scenes was conducted under clear (normal), inclement weather (fog) and glare conditions

It is important to realize that there are no absolute detection and identification distances for all targets to determine safety and efficacy. Actual visibility distances, excluding individual differences, will depend upon the target size, contrast (sign age, clean or dirty sign), background clutter (oncoming vehicle headlights, street and store lights) and vehicle headlight condition (low or high beams, clean or dirty lens). The NDS was designed to provide similar visibility distances to that of similar targets reported in the literature. One could use other targets in the real world and obtain other visibility distances; however, those distances would be relevant only for the conditions noted above such as age and condition of the target and would change over time. Therefore, safety and efficacy analysis can only be based on relative differences between the lenses, not absolute values. Visibility distance values could be biased to allow a very large difference between lenses to satisfy stopping distance requirements by making the simulator targets visible at very large distances or, conversely, visibility distance values could be biased to allow a very small difference between lenses to satisfy stopping distance requirements by making the simulator targets visible at very small distances. With this in mind, further analysis uses the actual target visibility distance examples first reported in the validation study literature for the NDS.

The ability of ReSTOR IOL patients to detect and identify road signs and hazards at night was similar to the monofocal controls under normal visibility driving conditions.

Sign Identification

Rural Driving Conditions
The mean visibility distances, standard deviation and percentage difference of monofocal and ReSTOR IOL subjects for sign identification under normal, fog and glare conditions in the rural scene are shown in Table 12.

Both fog and glare are seen to cause larger differences between the monofocal and ReSTOR lens subject performance than the clear night condition. However, in all instances the mean differences were less than 15%.

Table 12:
Mean (± SD) Sign Identification Distances in Rural Scene

Identification Distance (feet)		Lens		Difference	% Loss over Control
		Control	ReSTOR		
Visibility Condition	Targets				
Normal	Text	249 ± 57	230 ± 41	19	7.5 %
	Warning	523 ± 68	476 ± 81	47	8.9 %
Fog	Text	248 ± 42	215 ± 50	33	13.4 %
	Warning	512 ± 89	453 ± 88	60	11.6 %
Glare	Text	228 ± 56	195 ± 52	33	14.1 %
	Warning	512 ± 89	448 ± 83	64	12.5 %

City Driving Conditions
The mean visibility distances, standard deviation and percentage difference of monofocal and ReSTOR IOL subjects for sign identification under normal, fog and glare conditions in the city scene are shown in Table 13.

Under glare conditions, the ability of the ReSTOR lens subjects to identify the text sign is reduced on average by 28%, however there was only a small difference under these conditions for the warning sign.

Table 13:
Sign Identification Distances in City Scene

Identification Distance (feet)		Lens		Difference	% Loss Over Control
		Control	ReSTOR		
Visibility Condition	Targets				
Normal	Text	160 ± 30	143 ± 31	17	10.8 %
	Warning	211 ± 26	201 ± 25	10	4.7 %
Fog	Text	159 ± 24	138 ± 34	21	13.2 %
	Warning	208 ± 23	184 ± 31	24	11.7 %
Glare	Text	142 ± 33	102 ± 46	40	28 %
	Warning	194 ± 26	170 ± 28	24	12.5 %

Detecting Hazards

Rural Conditions
The mean visibility distances, standard deviation and percentage difference of monofocals and ReSTOR IOLs for hazard detection under normal, fog and glare conditions in the rural scene are shown in Table 14. All differences were less than 20%.

Table 14:
Hazard Detection Distances in Rural Scene

Detection Distance (feet)	Lens		Difference	% Loss Over Control
	Control	ReSTOR		
Visibility Condition				
Normal	511 ± 80	474 ± 87	37	7.2 %
Fog	507 ± 92	465 ± 101	42	8.5 %
Glare	480 ± 98	386 ± 150	94	19.7 %

City Conditions
The mean hazard detection, standard deviation and percentage differences for control and ReSTOR IOL subject groups for hazard detection under normal, fog and glare conditions in the city scene are shown in Table 15. In all instances the mean differences were less than 15%.

Table 15:
Hazard Detection Distances in City Scene

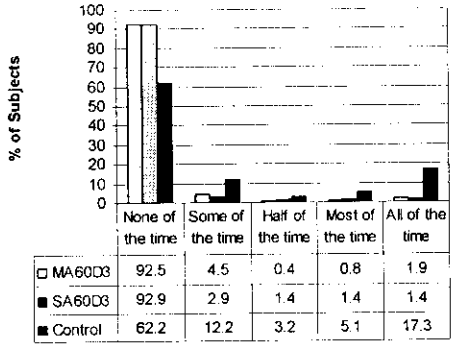
Detection Distance (feet)	Lens		Difference	% Loss Over Control
	Control	ReSTOR		
Visibility Condition				
Normal	200 ± 52	183 ± 38	17	8.5 %
Fog	229 ± 66	211 ± 65	18	7.9 %
Glare	190 ± 67	166 ± 48	24	12.6 %

Retinal Detail
No difficulties in retinal treatment were encountered by any investigator in the study. However, one investigator had 20 reports of loss of retinal detail (i.e., the fundus appeared more anterior).

Quality of Life/Spectacle Independence

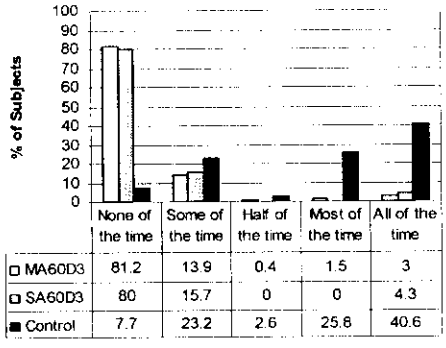
Patient reported spectacle independence was determined using the Cataract TyPE Specification instrument (Javitt, 1997). ReSTOR® IOL spectacle independence rates were statistically better ($p<0.0001$) than the control rates.

Figure 6:
Frequency of Spectacle Wear
Distance Vision, Bilateral Comparison



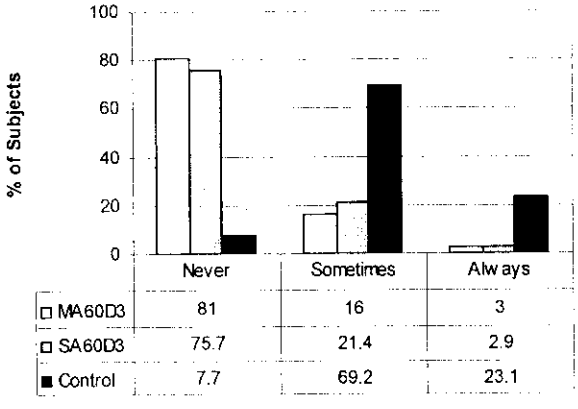
	None of the time	Some of the time	Half of the time	Most of the time	All of the time
MA60D3	92.5	4.5	0.4	0.8	1.9
SA60D3	92.9	2.9	1.4	1.4	1.4
Control	62.2	12.2	3.2	5.1	17.3

Figure 7:
Frequency of Spectacle Wear
Near Vision, Bilateral Comparison



	None of the time	Some of the time	Half of the time	Most of the time	All of the time
MA60D3	81.2	13.9	0.4	1.5	3
SA60D3	80	15.7	0	0	4.3
Control	7.7	23.2	2.6	25.8	40.6

Figure 8:
Overall Frequency of Spectacle Wear, Bilateral Comparison



	Never	Sometimes	Always
MA60D3	81	16	3
SA60D3	75.7	21.4	2.9
Control	7.7	69.2	23.1

Table 16:
Patient Satisfaction with Vision (without glasses)

		MA60D3	SA60D3	Control
Overall	Baseline	0.6 (N=311)	0.5 (N=126)	0.6 (N=193)
	Unilateral	2.6* (N=309)	2.5 (N=124)	2.4 (N=184)
	Bilateral	3.5** (N=268)	3.4** (N=69)	3.0 (N=155)
Day Vision	Baseline	0.9 (N=311)	0.7 (N=126)	0.8 (N=194)
	Unilateral	2.7* (N=309)	2.6 (N=123)	2.5 (N=185)
	Bilateral	3.5** (N=269)	3.4** (N=68)	3.0 (N=156)
Night Vision	Baseline	0.6 (N=311)	0.5 (N=126)	0.6 (N=193)
	Unilateral	2.4 (N=309)	2.5 (N=124)	2.4 (N=185)
	Bilateral	3.3** (N=269)	3.2* (N=69)	2.9 (N=156)

Satisfaction Scale (0-4): 0=not at all satisfied, 4=completely satisfied.
* = Significantly different from control at 0.05 level.
** = Significantly different from control at 0.01 level

Table 17:
Self Rating of Vision (without glasses)

	MA60D3	SA60D3	Control
Baseline	4.2 (N=313)	4.1 (N=125)	4.1 (N=194)
Unilateral	7.1 (N=307)	7.1 (N=123)	6.9 (N=185)
Bilateral	8.7* (N=266)	8.9* (N=70)	7.9 (N=155)

Rating Scale (0-10): 0=worst possible vision, 10=best possible vision
* = Significantly different from control at 0.01 level

Adverse Events
The incidence of cumulative adverse events for the ReSTOR® IOL compared favorably to the FDA historical grid rates. A single occurrence of pupillary block exceeded the FDA Grid rate. No occurrences of persistent adverse events were observed in any patients implanted with the ReSTOR® IOL.

Table 18:
ReSTOR® IOL versus FDA Historical Grid, First Eye - Safety

	ReSTOR MA60D3 (N=440)		ReSTOR SA60D3 (N=126)		FDA Grid rate*
	N	%	N	%	%
Cumulative Adverse Events					
Endophthalmitis	0	0.0	0	0.0	0.1
Macular Edema	12	2.7	1	0.8	3.0
Retinal Detachment/Repair	0	0.0	1	0.8	0.3
Hyphema	0	0.0	0	0.0	2.2
Pupillary block	1	0.2	0	0.0	0.1
Lens Dislocation	0	0.0	0	0.0	0.1
Surgical reintervention	10	2.3	2	1.6	0.8
IOL replacement for biometry error	2	0.5	0	0.0	NA
IOL replacement for incorrect power/ operating room error	2	0.5	0	0.0	NA
IOL replacement for visual disturbance	1	0.2	0	0.0	NA
IOL replacement for decentered IOL due to trauma	1	0.2	0	0.0	NA
IOL replacement due to patient dissatisfaction	0	0.0	1	0.8	NA
Laser treatment	3	0.7	1	0.8	NA
Fibrin removal	1	0.2	0	0.0	NA
Persistent Adverse Events:					
Macular Edema	0	0.0	0	0.0	0.5
Raised IOP Requiring Treatment	0	0.0	0	0.0	0.4
Corneal Edema	0	0.0	0	0.0	0.3
Iritis	0	0.0	0	0.0	0.3

*FDA draft guidance on Monofocal Intraocular Lenses, Annex B (October 14, 1999)

Visual Disturbances
In every category of visual disturbance evaluated, ReSTOR® IOL patients reported a rate of severe observation no greater than their Monofocal Control counterparts (Table 19). Of the 440 subjects implanted with ReSTOR Model MA60D3 and 126 subjects implanted with Model SA60D3, one subject implanted with ReSTOR Model MA60D3 required lens explantation due to visual disturbances.

Table 19:
Visual Disturbances, 6 Months Postoperative
(Following second eye implantation)

Visual Disturbance	ReSTOR Model MA60D3		ReSTOR Model SA60D3		Monofocal Control	
	% Moderate	% Severe	% Moderate	% Severe	% Moderate	% Severe
Glare/Flare	20.1	4.9	23.2	4.3	7.1	1.9
Problems with Night Vision	8.5	4.1	10.1	2.9	3.8	1.9
Halos	18.0	4.4	23.2	7.2	1.9	1.3
Distorted Near Vision	0.8	0.8	0.0	0.0	0.6	0.0
Distorted Far Vision	1.0	0.3	0.0	0.0	0.6	0.0
Blurred Near Vision	5.9	0.8	7.2	0.0	12.8	3.8
Blurred Far Vision	5.9	1.0	5.8	0.0	3.2	0.6
Double Vision in both eyes	1.5	0.8	1.4	0.0	1.3	0.0
Problems with Color Perception	0.5	0.0	0.0	0.0	0.0	0.0

HOW SUPPLIED
The ACRYSOF® ReSTOR® IOL is supplied dry, in a package terminally sterilized with ethylene oxide, and must be opened only under aseptic conditions (see DIRECTIONS FOR USE).

EXPIRATION DATE
Sterility is guaranteed unless the pouch is damaged or opened. The expiration date is clearly indicated on the outside of the lens package. Any lens held after the expiration date should be returned to Alcon Laboratories, Inc. (See RETURNED GOODS POLICY).

RETURNED GOODS POLICY
In the United States, returned lenses will only be accepted in exchange for other products, not credit. All returns must be accompanied by an Alcon Laboratories, Inc. Returned Goods Number and be shipped via traceable means. A Returned Goods Number is obtained by contacting Alcon's Customer Service Department. Issuance of this number does not constitute final acceptance of the returned products. For detailed policy guidelines including exchange, please contact your Sales or Customer Service Representative. Outside the United States, contact local Alcon offices or distributors regarding returned goods policy.

REFERENCES
Boettner, E.A. and Wolter, J.R., Transmission of the Ocular Media. Invest. Ophthalmol. 1:776-783, 1962.

Symbols Used on Labeling

SYMBOL	ENGLISH
IOL	Intraocular lens
PC	Posterior chamber
PCL	Posterior chamber lens
UV	Ultraviolet
ADO	Apodized Diffractive Optic
D	Diopter
$Ø_B$	Body diameter (Optic diameter)
$Ø_T$	Overall diameter (Overall length)
2	Do not reuse
⧖	Use by (YYYY-MM: year-month)
STERILE EO	Sterilized by ethylene oxide
SN	Serial Number
⚠	Attention: See instructions for use

Manufacturer:
Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, Texas 76134-2099 USA